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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,242	12/18/2000	James Varani	1718-012	4901

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1615	
MAIL DATE	**DELIVERY MODE**
09/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/740,242	VARANI ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *1-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of response and terminal disclaimer filed on 6-19-07 is acknowledged.

Claims 1-15 are pending. Claims 1-7 have been withdrawn as being non-elected and claims 8-15 have been examined.

Terminal Disclaimer

The terminal disclaimer filed on 6-19-07 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US patents 6,130254, 6683069, 7141238, 6630516 and 6919072 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

Applicant's arguments filed 6-19-07 have been fully considered but they are not persuasive.

3. Claims 6-15 are directed to an invention not patentably distinct from claims1-13 of US Patent No. 6,130,254; claims 1-23 of US Patent No. 6,683,069; claims 1-38 of US 6,630,516 claims 1-18 of US Patent 6,919,072 and claims 1-12 of US Patent 7,141,238, all of which are commonly assigned US Patents.

6. Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,837,224, US 6,130,254, US Patent No. 6,683,069; US 6,630,516, US 6,919,072 and US Patent 7,141,238.

Applicants state that the instant claims differ from each of the above references, singly or in combination, by requiring the selectivity inhibition of MMP-1 versus MMP-2 and/or MMP-9. It is argued that the teachings of '224 is contrary to the claimed method based on the Figs. 5B and 5E (the 72kDa gelatinase is MMP-2 and the 92kDa gelatinase is MMP-9; see application at page 3, and Whittaker *et al.* at p. 2737), in which inhibition of MMP-2 and MMP-9 is successful for inhibiting photoaging.

It is argued that contrary to the claimed invention, in the '254 patent, Figs. 11A, 12, and 13C-13D, showing that UV radiation induces MMP-2 and MMP-9 with the intent of inhibiting its action (e.g., Fig. 15A). Applicants argue that none of these citations teach or suggest the selective inhibition presently claimed. Pages 2766-2768 of the Whittaker *et al.* article describes various disease models in which MMPs are active, but none of these related to photoaging or chronological aging of human skin. It is argued that absent experiments such as described in this application, and based on the cited art's teaching to inhibit all of the MMPs induced by photoaging or chronoaging, it would have been unexpected that any advantage could be obtained by selectively inhibiting MMP-1 versus MMP-2 and/or MMP-9. Accordingly, this rejection should be withdrawn. Applicants arguments are not persuasive because instant claims have been rejected over the above-patented claims based on the same reasoning that has also been used in rejecting the claims under 35 USC 103(a). Applicants filed a terminal disclaimer over the above patents to obviate the rejection, however, argues that the teachings of the above patents are contrary to that of the instant invention. Further, applicants' arguments are not persuasive because while patent '224 teaches inhibition of MMP-9,

the above patent also describes inhibition of MMP-1 and thus meet the claim limitations. With respect to '254, applicants interpret that '254 teaches inhibition of MMP-2 and MMP-9, with the intent of inhibiting the two MMPs. However, '254 show inhibition of collagenase, which according to page 3 of the instant disclosure is MMP-1 and hence meets the claimed conditions. Applicants' argument that '069 and '238 patents are directed to preventing a reduction in collagen biosynthesis and that there is nothing to suggest reducing the deleterious effects of inhibiting MMP-2 and/or MMP-9 as claimed in this application, is not persuasive. '069 and '238clearly states that MMPs inhibit the biosynthesis of collagen and also cause its degradation. Thus, any inhibition of the MMPs (in ;069 and '238) to prevent the inhibition of collagen biosynthesis also inhibits collagen degradation, unless shown to the contrary. For the teachings of '516 and '072, it is argued that the patents are directed to chronological aging in skin. Figs. 4B and 4C, and the accompanying disclosure, showing that these enzymes are more prevalent in aged skin and teaching, therefore, it would be beneficial to inhibit them. Applicants' arguments are not persuasive because '516 recognizes the degradation of collagen by MMPs. Moreover, instant claim 8 also recites chronologically aged skin and hence the reads on the instant claims. Finally, all of the above patents recognize the role of MMPs in collagen degradation in the skin of aged (photo or chronological) people and also recognize their inhibition and hence it would have been obvious for a skilled artisan to employ a known inhibitor of MMP to prevent or inhibit collagen degradation in aged skin cells.

4. Clams 8-15 are rejected under35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain the subject matter, which was not described in such a way as o reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that the rejection is confusing because while the rejection alleges that the specification does not describe the compounds, it is acknowledged that three such compounds are disclosed. Examiner acknowledges that three compounds identified by compounds 28, 52 and 53 have been recited in the instant disclosure for their selective activity against MMPs. However, instant claims are limited to a specific compound. Instant disclosure does not provide description or structure of any other compounds that may possess the claimed activity. While one of an ordinary skill in the art would understand from the instant disclosure that the above compounds possess the claimed activity, the breadth of the claims is not limited to the above compounds and therefore a skilled artisan would not readily understand what are all the compounds that may be employed to practice the instant invention. With respect to the examples, according to the instant disclosure the three compounds of Whittaker inhibit MMP selectively. However, instant claims are not directed to their inhibition and instead claims inhibition or reducing of collagen degradation, improving collagen biosynthesis, improving collagen and fibroblast proliferation. The specification does not provide any description or examples of what amounts, or percentages or concentrations of the compounds

possibly render the claimed methods or to what extent the selective inhibition of MMPs occur so as to ensure the desired inhibition or reduction in collagen degradation.

With respect to the lack of enablement, it is argued that the rejection does not explain why one skilled in the art could not make suitable compositions as claimed, given the knowledge of the selectivity of 139 different compounds of Whittaker with respect to inhibiting different MMPs (by determining the mere inhibitory concentration required). It is argued that applicants are not claiming a novel genus of compounds or a compound and instead the compounds are known. Applicants' arguments are not persuasive because, instant claims do not recite any specific compound or compounds and reads on any compound that possess the claimed selectivity (not necessarily from those described by Whittaker). According to instant specification not all of the compounds described by Whittaker possess the selective inhibition of MMP-1 (page 11). Applicants further state that while experiments have been performed with MMP-1, MMP-8 and 13 are likely to be as detrimental as MMP-1. Thus, instant specification do not teach or provide guidance as to what compounds possess the selective inhibition of MMP-8 or MMP-13 over MMP-9, what is the extent of selectivity of inhibition (percentage difference) that the compounds should possess such that the claimed reduction or inhibition of collagen degradation or biosynthesis occurs. Absent such guidance, together with the lack of any working examples, a skilled artisan would have to perform undue experimentation to practice the claimed methods because not all MMP inhibiting compounds (according to the specification) possess the ability to selectively inhibit MMPs.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
September 12, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER